ATTACHMENT A
Remarks

Claims 1-13 are pending in the present application. By this amendment, applicants have amended claims 1 and 3 and canceled claims 15 and 16. Applicants respectfully submit that the application is condition for allowance based on the discussion which follows.

Claim 3 was objected to on informality grounds for failing to include "group of" after the words "from the". By this amendment, applicants have amended claim 3 as suggested by the Examiner thereby obviating the objection.

Claims 1, 6, 11, 13, 15 and 16 were rejected under 35 U.S.C. §112, first paragraph, for failing to provide a sufficient written description which would reasonably convey to one of ordinary skill in the art that the applicants had possession of the claimed invention at the time the instant application was filed. The Examiner alleges that the specification discloses only a single peptide sequence species of the claimed peptide genus, namely, the polypeptide SEQ ID No. 4. The Examiner further contends that the specification is silent as to the structure/function relationship for a polypeptide comprising an amino acid sequence that is encoded by SEQ ID No. 3 and that the function SEQ ID No. 4 is not disclosed. However, the Examiner acknowledges that the previously filed declaration under Rule 132 establishes the function of the genus of the polypeptides (i.e., SEQ ID No. 4) which is the function of neprilysin. Based on the Examiner's finding that the specification is silent with regard to the structural attributes and features of the claimed genus, the Examiner concluded that one skilled in the art would not conclude that the applicant had possession of the claimed invention at the time this application was filed.

Contrary to the Examiner's conclusion, the present specification does provide structural attributes and features of the claimed genus. Along with the previously established function of the claimed genus, the present specification does allow one skilled in the art to conclude the applicants possessed the claimed invention at the time the application was filed.

In order to more clearly establish applicants as being in possession of the claimed invention, applicants have amended claim 1 to provide further structure of the claimed polypeptide whose function has already been established and acknowledged by the Examiner as being in the possession of the applicants at the time of the filing the present application. Applicants respectfully submit that the specification as filed provides sufficient structural attributes and features of the claimed genus as the specification discloses the structural feature of the claimed invention as belonging to the enzyme/neprilysin/Kell family on page 1, lines 28-32. By this amendment, claim 1 affirmatively recites this additional structure previously disclosed and thus not new matter.

Moreover, one of ordinary skill in the art would readily appreciate and easily discern the structure of the claimed polypeptide recited as having an amino acid sequence encoded by nucleic acid sequence SEQ ID No. 3 where the polypeptide is a membrane-bound metalloprotease referred to as NEP2 and belonging to the enzyme/niprilysin/Kell family. Specifically, the specification allows one skilled in the art to determine the sequence of the NEP2 polypeptide and thus the structure of the claimed polypeptide.

Furthermore, functional features taught by the instant application would have made it possible for the one skilled in the art to confirm that the isolated polypeptide that comprises an amino acid encoded by SEQ ID No. 3 had the required human NEP2 activity.

As recited in claim 1, NEP2 belongs to ECE/NEP/Kell family, which means that human NEP2 shares substrate and inhibitor specificity with known enzymes belonging to the ECE/NEP/Kell family, such as the prototypical member niprilysin (NEP). This was actually demonstrated by the inventors of the present invention who showed that human NEP2 processes synthetic and natural substrates known to be hydrolyzed by neprilysin, as reported in the Rule 132 Declaration from Tanja Ouimet.

Additionally, the one skilled in the art could have readily made sure that the isolated human NEP2 had same substrates and inhibitors as the homologous rat NEP2 protein which is described in the application. As previously discussed in the Rule 132 Declaration from Tanja Ouimet, rat and human NEP2 have similar proteolytic activity and inhibitory pattern.

Accordingly, the specification of the instant application discloses all necessary structural and functional features defining the claimed NEP2 polypeptide, as one of ordinary skill in the art would be aware of the structure of the polypeptide encoded by SEQ ID No. 3.

Based on the foregoing, applicants have established that they were possession of the instant invention at the time that the application was filed by establishing both the function of the claimed polypeptide, as acknowledged by the Examiner in the outstanding Office Action and, by the foregoing remarks, the structural features of the

claimed polypeptide. Therefore, applicants respectfully request that the Examiner withdraw the rejection to claims 1, 6, 11, 13, 15 and 16 under 35 U.S.C. §112, first paragraph.

Claims 2, 4 and 5 were rejected under 35 U.S.C. §112, first paragraph. The Examiner alleges that the specification, while being enabling for DNA identified by SEQ ID No. 3, does not reasonably provide enablement for all DNA molecules that comprise SEQ ID No. 3.

Applicants respectfully submit that claims 2, 4 and 5 are fully enabled under 35 U.S.C. §112, first paragraph as the specification as filed discloses nucleic acid compounds comprising SEQ ID No. 3 which include specific examples of isolated nucleic acids such as expression vectors and host cells transformed with the expression vector. One of ordinary skill in the art would readily appreciate the structure and function of the claimed isolated nucleic acid (claim 2), expression vector (claim 4) and transferred host cell (claim 5). Thus, applicants have provided guidance in the form of examples to establish the Applicants had possession of the claimed invention at the time the application was filed.

Furthermore, the present specification does describe how to encode a polypeptide with the disclosed functionality using SEQ ID No. 3 to practice the claimed inventions of claims 2, 4 and 5. For example, the specification at page 5, states that the nucleotide sequences of the present invention can be used to produce the NEP2 protein using conventional techniques in the art such as through an expression vector. Further, the specification discloses that the vector should include a promoter, a translation initiation and termination signals, and a suitable transcription regulation region. Thus,

this specification does provide guidance and examples as to the structure and function of the claimed DNA molecule comprising SEQ ID No. 3 and host cell transformed, and how to construct it so that it has the capacity for encoding a polypeptide with the disclosed functionality.

Based on the foregoing, applicants respectfully request that the Examiner withdraw the rejection to claims 2, 4 and 5 under 35 U.S.C. §112, first paragraph.

Claim 6 was rejected under 35 U.S.C. §102(b) as being anticipated by Shipp et al. (hereinafter "Shipp") and Ritz et al. (hereinafter "Ritz"). Claim 6 is now anticipated by Shipp or Ritz as Shipp and Ritz fail to teach or suggest the claimed monoclonal or polyclonal isolated antibodies capable of recognizing specifically a peptide of claim 1. On the contrary, Shipp and Riz clearly teach antibodies which react with additional polypeptides other than the polypeptide according to claim 1. Thus, the antibodies of Shipp and Ritz are not "capable of recognizing specifically a peptide of claim 1." Since the antibodies disclosed in Shipp et al. and Ritz et al. fail to be specific, i.e., only bind, and recognize the polypeptide of claim 1, the disclosed antibodies in Shipp et al., Ritz et al. do not anticipate the antibodies of claim 6. Therefore, applicants respectfully request that the rejection to claim 6 as being anticipated by Shipp et al. and Ritz et al. under 35 U.S.C. §102(b) be withdrawn.

In view of the foregoing, applicants respectfully submit that the application is in condition for allowance.

END OF REMARKS